AF/3738/ #120

Atty Dkt. **213202.00271**

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: Bruce Snow
DONALD R. RICCI ET AL.	)	
	:	Group Art Unit: 3738
Application No.: 09/744,916	)	
	:	Confirmation No. 8554
Filed: January 31, 2001	)	
	:	
For: SMALL VESSEL EXPANDABLE STENT AND METHOD FOR PRODUCTION OF SAME	)	June 10, 2004

Mail Stop Appeal Brief -Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF ON APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

Enclosed are three copies of Appellant's Brief on Appeal. The Commissioner is authorized to charge Deposit Account No. 50-1710 for the fee required by 37 CFR §1.17(c).

REAL PARTY IN INTEREST

The real party in interest to this application and to this appeal is the evYsio Medical Device ULC.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 32-59 are pending in the present application. Claims 32, 41, 45 and 48 are independent.

Claims 32-55 were finally rejected under 35 U.S.C. §102(e) as being purportedly anticipated by United States patent 5,843,117 [Alt et al. ("Alt")], and Claims 56-59 were finally rejected under 35 U.S.C. §103(a) as being purportedly unpatentable over Alt, as set forth in the May 8, 2003 final Office Action (hereinafter referred to as "the final Office Action"). Applicants appeal the final rejection.

Claims 32-59 are reproduced in the Appendix submitted herewith.

STATUS OF AMENDMENTS

All amendments have been entered.

SUMMARY OF THE INVENTION

The present invention relates to an expandable stent particularly designed for use in small diameter body passageways. Thus, each of the independent claims recites a novel combination of structure and/or function whereby the stent is expandable to **a maximum yield point** when the tubular wall of the stent has a diameter of **less then or equal to about 3.5 mm**. The term "maximum yield point" is specifically defined in the specification in the second full paragraph of page 4.

As discussed in the specification, the present invention has particularly utility in small body passageways where larger stents will likely recoil (shrink) after expansion, leading to an improperly implanted stent. The problems of using conventional stents in small body passageways is

detailed in the specification from the second full paragraph on page 4 to the third full paragraph on page 5. For the convenience of the Board of Appeals, attached herewith is a "Stress Strain Curve for Ductile Material", to graphically illustrate the principles discussed in the specification. This graph was previously submitted with the Amendment filed February 28, 2003.

ISSUE

The principle issue for consideration of the Board of Appeals in this matter is whether Claims 32-55 are anticipated by Alt under 35 U.S.C. §102(e).[1]

Briefly, in the final Office Action, the Examiner states the following:

> "Applicant's invention as claimed in claim 1, is that their stent can be fully expanded to the maximum yield point. **The underlying fact is that any prior art stent can be expanded to the diameter where it reaches the maximum yield point. The maximum yield point is a characteristic of the material used. Further, applicant uses the materials which are well known in the art.** Applicant claimed "invention" [*sic*] is merely a functionally limitation [*sic*] which does patentably differentiate the stent". (Emphasis in the original).

In the final Office Action, these statements appear to be the basis of the rejection.

GROUPING OF CLAIMS

For the purposes of this appeal, Claims 32-59 maybe grouped together.

[1] Applicants continue to traverse the objection to the drawings on the grounds that the claimed "porous surface defined by a plurality of interconnecting struts" does not have to be shown in the Drawings since such structure is notoriously well known and thus not "necessary for the understanding of the subject matter sought to be patented.", as specified by 37 C.F.R. § 1.81(a). Indeed the final rejection makes clear that the Examiner fully understands such structure.

ARGUMENTS

Briefly, the Examiner has failed to correctly construe the independent claims of the present application, particularly, the Examiner has failed to consider the claim limitation "when the tubular wall has a diameter of less then or equal to about 3.5 mm." In the final Office Action, the Examiner states that the present invention is one in which the "stent can be fully expanded to the maximum yield point". This is clearly incorrect.

Alt is nothing more than the prior art discussed at page 5 of the specification. Specifically, Alt fails to disclose or suggest that the stent is expandable to **a maximum yield point** when the tubular wall has a diameter of **less than or equal to about 3.5 mm**. In fact, Alt does not even inherently suggest this structural feature of the present invention, and actually teaches away from the Applicants' solution to the small passageway stent problem. For example, Alt teaches at Column 16, lines 58-60 that his stent is expandable "in a range from about 2.5 to about 5.0 mm, with a maximum of about 6.0 mm." Thus, Alt's maximum expansion point (presumably its maximum yield point) is between 5.0 and 6.0 mm. If the Alt stent were expanded to 3.5 mm, this would place it in the elastic region of the attached graph. As described at page 5 of the subject application, such a stent would likely experience recoil, shrink slightly, and fail to be properly implanted. Stated another way, the Alt stent expanded to less than about 3.5 mm could not have reached its **maximum yield point**. Therefore, Alt fails to disclose or suggest a stent having **a maximum yield point** when the tubular wall has a diameter of **less than or equal to about 3.5 mm**.

It should be emphasized that, as stated in the second full paragraph on page 4 of the specification, the term "maximum yield point" is intended to mean the point on a stress strain profile above which increased expansive force can be applied to the stent to further expand the stent resulting in a decrease in a cross sectional area of the expanding material. This leads to catastrophic failure of the stent. Accordingly, the actual deployed diameter of the stent would be less then 3.5 mm.

A stent having such features was the subject of a long felt want in the art but was not fulfilled by Alt.

For independent validation of this point, Applicants attach hereto a copy of a press release dated April 19, 1999 from Cordis Cardiology, one of the leading manufacturers and distributors of stents in the United States. This press release states inter alia:

> "Historically, most smaller vesseletions have been treated with balloon antioplastio alone due to the small lumen size of these vessels and the increased risk of disection. Doctor Williams noted that the use of large-vessel stents systems and small-vessels generally doesn't allow for a proper stent-to-artery ratio when deployed".

Alt is nothing more then another teaching of a so-called large-vessel stent system.

A patent application claim is anticipated, and therefore invalid under 35 U.S.C. § 102, if a single prior art reference discloses, either expressly or inherently, each and every limitation of the claim. *Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995). Quite simply the Examiner has failed to meet his burden of establishing that each and every feature of the independent claims is present in Alt.

Under 35 U.S.C. § 103, the examiner has the burden of establishing a *prima facie* case of obviousness, by evidencing (i) some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference (ii) a reasonable expectation of success, and (iii) that the prior art reference teaches or suggests all of the claim limitations. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Again, the Examiner has failed to meet his burden of establishing a prima facie case since nothing in Alt suggests the claimed features whereby the stent has **a maximum yield point** when the tubular wall has a diameter of **less than or equal to about 3.5 mm**.

In the final Office Action, the Examiner states that "Applicant's invention as claimed in claim 1, is that their stent can be fully expanded to the maximum yield point". The Examiner goes on to state that the "maximum yield point is a characteristic of the material used". Applicant agrees with this latter statement. Applicant disagrees that what is being defined in the present independent claims is a stent that can be fully expanded to its maximum yield point, per se.

Rather, Applicant claims an unexpanded stent having a tubular wall that is capable of undergoing plastic deformation to a maximum yield point when the tubular wall has a diameter of less then or equal to about 3.5 mm. **Applicant is not claiming an inherent property of the material, per se. Rather, Applicant is claiming a device characterized by manifestation of that property in prescribed structure – i.e., below a prescribed diameter of the tubular wall of the stent.**

With further reference to Alt, notwithstanding the arguments made above, Applicant submits that Alt does not teach a stent having each and every element defined in the independent claims in the present application. Further, Alt does not teach or suggest a stent that would inevitably fall within the claims of the present application. The Alt stent is expandable "in a range from about 2.5 to about 5.0 mm, with a maximum of about 6.0 mm". As discussed above and in the preamble of the present application, since catastrophic stent failure would be expected to occur at a diameter beyond the maximum yield point of the material used to construct the stent, it would be impossible for Alt to teach a device having a maximum yield of less then 3.5 mm if the maximum diameter of expansion is 6.0 mm. Put in another way, if Alt truly taught a maximum yield point of less then 3.5 mm, he would be inviting catastrophic stent failure by teaching that the deployable diameter of stent can be as high as 6.0 mm. Clearly, Alt is an example of the so-called "large-vessel stent systems" referred to in the Cordis press release described above. A stent which is intended to be expanded to a maximum of 6.0 mm as specified by Alt simply cannot have a maximum yield point of 3.5 mm – such a device would fail in vivo. The present independent claims do not encompass a stent having an expansion diameter range that exceeds 3.5 mm.

CONCLUSION

In view of the above, Appellants submit that independent Claims 32, 41, 45 and 48 are not anticipated by Alt under 35 U.S.C. §102(e). In addition, each of Claims 33-40, 42-44, 46, 47 and 49-59 depends from one of the four independent claims, and are each allowable as being dependent from an allowable base claim. Accordingly, reversal of the final rejection, allowance of the rejected claim, and issuance of the subject patent application are respectfully requested.

Appellants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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APPENDIX

32. An unexpanded stent comprising:

a proximal end and a distal end in communication with one another,

a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts,

the stent being expandable upon the application of a radially outward force thereon to undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

33. The unexpanded stent defined in claim 32, wherein the stent is expandable:

from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation; and

from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

34. The unexpanded stent defined in claim 33, wherein, in the second pre-expanded position, the stent has a diameter greater than about 1.1 mm.

35. The unexpanded stent defined in claim 33, wherein, in the second pre-expanded position, the stent has a diameter sufficiently large for the stent to receive expansion means to further expand the stent.

36. The unexpanded stent defined in claim 33, wherein, in the first unexpanded position, the stent has a diameter less than or equal to about 1.1 mm.

37. The unexpanded stent defined in claim 33, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about 1.1 mm.

38. The unexpanded stent defined in claim 33, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about 1.0 mm.

39. The unexpanded stent defined in claim 32, wherein the tubular wall has a substantially circular cross-section.

40. The unexpanded stent defined in claim 32, wherein the tubular wall is constructed of a plastically deformable material.

41. A partially expanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

having been expanded by the application of a radially outward force thereon from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and

being further expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

42. The partially expanded stent defined in claim 41, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.3 mm.

43. The partially expanded stent defined in claim 41, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter in the range of from about 2.2 to about 3.3 mm.

44. The partially expanded stent defined in claim 41, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter in the range of from about 2.5 to about 3.0 mm.

45. A stent delivery kit comprising:

a catheter;

an expandable member disposed on the catheter; and

the partially expanded stent defined in claim 41 disposed on the catheter

46. The stent delivery kit defined in claim 45, wherein the stent is mechanically mounted on the expandable member.

47. The stent delivery kit defined in claim 46, wherein the stent is crimped onto the expandable member.

48. A method for mounting an unexpanded stent on a catheter having an expandable member disposed thereon, the unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon:

(i) expanding the unexpanded stent to a second pre-expanded position at which the stent has reached a point of plastic deformation to produce a partially expanded stent, the unexpanded stent being configured such that it has a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm; and

(ii) placing the partially expanded stent on the expandable member of the catheter.

49. The method defined in claim 48, wherein Step (i) comprises urging the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

50. The method defined in claim 48, wherein Step (i) comprises pushing the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

51. The method defined in claim 48, wherein Step (i) comprises pulling the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

52. The method defined in claim 50, wherein the mandrel is tapered.

53. The method defined in claim 48, wherein Step (i) comprises urging the stent over a die in a direction substantially parallel to the longitudinal axis.

54. The method defined in claim 48, wherein Step (i) comprises placing the stent over an expandable means, and thereafter expanding the stent to the second pre-expanded position.

55. The method defined in claim 48, wherein Step (ii) comprises crimping the partially expanded stent on to the expandable member of the catheter.

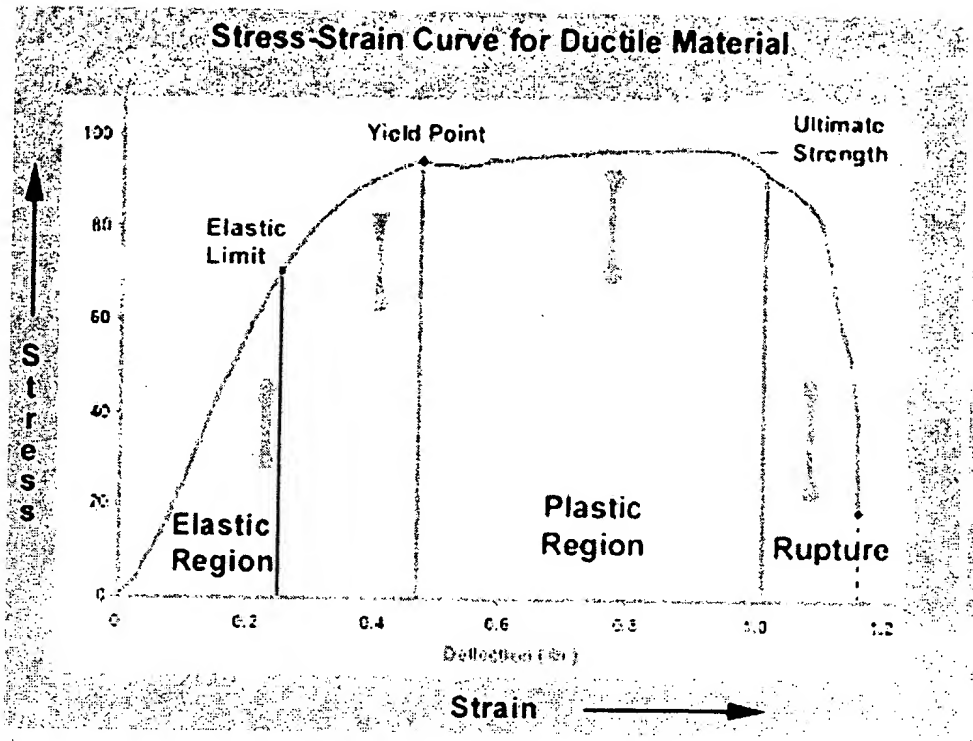
56. An unexpanded stent according to claim 32, wherein said tubular wall has a medicinal coating disposed thereon.

57. A partially expanded stent according to claim 41, wherein said tubular wall has a medicinal coating disposed thereon.

58. A stent kit according to claim 41, wherein said tubular wall has a medicinal coating disposed thereon.

59. A method according to claim 48, wherein the stent has a medicinal coating disposed thereon.

Stress-Strain Curve for Ductile M rial



Elastic Limit

Young's Modulus

Yield Point

Ultimate Strength

Rupture

Elastic Region

Plastic Region

Read the explanation for this term

Resilience

Toughness

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News / News Archive

Cordis Cardiology Introduces the MINI Crown Stent

FDA Clears New Coronary Artery Stent Specifically Engineered For Smaller Vessels

Miami, FL (April 19, 1999) – Cordis Cardiology today reported it received approval from the U.S. Food and Drug Administration to market its new MINI Crown stent (the MINI) specifically engineered for smaller coronary vessels (lumen diameters from 3.25 mm to as small as 2.25 mm). Cordis Cardiology is a unit of Cordis Corporation, a Johnson & Johnson company.

According to David O. Williams, M.D., Division of Cardiology, Rhode Island Hospital, Providence, RI, who served as principal investigator in the clinical trial of the MINI, many physicians view smaller vessel stenting as the next frontier in interventional cardiology.

"There's no question there is high physician demand for a quality smaller vessel stent," said Dr. Williams. "I find the MINI to be the best choice for stenting smaller vessels. It offers many unique advantages, such as one-step deployment, a low-profile delivery system, minimal balloon overhang, and precise balloon sizing at higher pressures – all of which, in my opinion, make the procedure safe."

Jesse Penn, president, Cordis Cardiology, said the company initially will offer the MINI in 11-mm and 15-mm lengths and diameters ranging from 3.25 mm to 2.25 mm in quarter sizes. Mr. Penn described the MINI as the stent that enables physicians to 'go smaller safely,' predicting it will soon become the 'gold standard' for smaller vessel stenting.

Mr. Penn also explained the MINI and its Dynasty™ delivery system have been carefully designed to respond to the need for a stenting system that offers easy deliverability in patients with small, tight lesions while minimizing the risks of edge dissection and stent embolization.

"We're addressing the issue of edge dissection by 1) using the new non-compliant* DURAMAX™ balloon material to control expansion and 2) closely matching balloon and stent lengths to limit balloon overhang to 1 mm, thus greatly reducing the potential for what cardiologists describe as dog boning+," said Mr. Penn. "To minimize the risk of stent embolization, Cordis' proprietary Nesting™ technology secures the MINI to the delivery balloon until it is deployed."

"Clinical trial results show the MINI to be associated with a high rate of successful deployment, outstanding angiographic outcomes, and a very low rate of post-stenting major adverse cardiac events," said Dr. Williams. "While the MINI is an excellent stent

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major adverse cardiac events," said Dr. Williams. "While the MINI is an excellent stent for treating smaller vessels, I am also extremely impressed with its performance in vessels with lumen diameters of 3.0 mm to 3.25 mm."

Historically, most smaller vessel lesions have been treated with balloon angioplasty alone due to the small lumen size of these vessels and the increased risk of dissection. Dr. Williams noted the use of large-vessel stent systems in small-diameter vessels generally doesn't allow for a proper stent-to-artery ratio when deployed.

The MINI is indicated for treatment of abrupt or threatened closure in patients with failed interventional therapy in native coronary lesions (less than or equal to 25 mm) with reference diameters in the range of 3.25 mm to 2.25 mm.

Cordis Cardiology is a unit of Cordis Corporation, a broad-based supplier of products for circulatory disease management. Established in 1959, Cordis Corporation is the world's largest, most comprehensive developer and manufacturer of innovative products for interventional medicine, minimally invasive computer-based imaging, and electrophysiology. In 1996, Cordis Corporation merged with Johnson & Johnson to form Cordis, a Johnson & Johnson company, with approximately 3,500 employees worldwide.

*Non-compliant: Term used to describe balloon material that provides predictable and controllable expansion to minimize the risk of edge dissection.

+Dog boning: Term used to describe the appearance of excessive expansion of the balloon on either end of the stent.

NOTE TO EDITORS: To participate in an audioconference with Dr. David Williams and Cordis Cardiology senior management on Wednesday, April 21, from 10 - 11 a.m. (EDT), please call 1-800-670-3547 (at 10 a.m. EDT). If you have any problems getting a connection into the audioconference, please call D.J. Storch & Associates at 908-273-1400.

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Last Updated: April 13, 2004